



October 4, 2002

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-22

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics
Suite 104
510 South 17th Street
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

Subject: Issuance of a Conditional License for Bacterial Immunomodulator,
Killed Bacteria

To: Biologics Licensee, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Immune Modulators, Inc., Establishment No. 606, Cataula, Georgia, for the manufacture and distribution of Bacterial Immunomodulator, Killed Bacteria.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product may be issued. The regulations in 9 CFR Part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstances. The special circumstance addressed here is the absence of other licensed veterinary biological bacterial immunomodulators intended as an adjunct to antimicrobial therapy in the treatment of infectious respiratory disease in horses. In addition, the anticipated market for this product is believed to be limited.

This conditional license was issued following the acceptance of data supporting product purity, product safety under normal conditions of use (field safety), and demonstration that the product has a reasonable expectation of efficacy. This license will expire in one year. In accordance with 9 CFR Part 102, progress toward regular licensure must be pursued for reissuance of the conditional license.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



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